

K120492

510(k) Summary as required by section 807.92(c)

APR 30 2012

date prepared February 13th, 2012

Submission Applicant:

K2 Medical GmbH & Co.KG
Unter Buchsteig 3a
78532 Tuttlingen, GERMANY

Establishment Registration Number:

3007648354

Official Correspondent:

Mr. Peter Fetzer
K2 Medical GmbH & Co.KG
Unter Buchsteig 3a
78532 Tuttlingen, GERMANY

Phone: 049-7462-200-49-0

Trade name:

K2 Medical Vascular Clamp

Common name:

Various vascular clamps:

Bulldog Clamps, Vessel Clamps, Microvascular Bulldog Clamps, Ring Handle Bulldog Clamps, Neonatal Vascular Clamp, Pediatric Clamps, Occlusion Clamps, Vascular Clamps, Cardio Clamps, Aorta Clamps, Multi-Purpose Clamps, Blood Vessel Forceps, Anastomosis Clamps, Vena Cava Clamps, Peripheral vascular Clamps, Aortic Aneurysm Clamps, Abdominal Clamps, Artery Clamps, Profunda Clamps, Shunt Clamps, Aortic Clamps, Patent-Ductus Clamps, Fogarty-Type Clamps, Vascular Forceps, Microvascular Forceps, Minimally Invasive Coronary Systems

Classification name:

Clamp, Vascular (21 CFR 870.4450, Product code DXC)

Regulation Description

Vascular Clamp

Substantial Equivalence Claims:

K092544 INSTRUMED VASCULAR CLAMPS

INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Description of the Device:

The K2 Medical Vascular Clamps are reusable surgical instruments.

To ensure the multi-purpose use of this device, many different models are available. The differences can be as follows:

- Some have ring handles with a ratchet closure to adjust the amount of tension applied to the vessel for occlusion or partial occlusion.
- Bulldog style Vascular Clamps are another type of vascular cross clamp that use a spring or cross action mechanism to apply tension to the vessel for occlusion.
- The choice of jaw style depends on the surgeon's preference, based on the type and delicacy of the vessel to be occluded.

The surgeon chooses the vascular clamp based on the anatomy of the site and the type of occlusion desired, based on the type and size of the blood vessels, and surgical techniques.

Clamps are either fully or partially occluding an artery or vein with correct tension to produce minimal trauma to vessels. Full occlusion clamps stops blood flow entirely by covering the full vessel. Partial occlusion clamps are placed on part of the vessel to isolate the area to be worked on while allowing blood flow to continue in the rest of the vessel.

K2 Medical vascular clamps are made of the following standardized materials
Stainless Steel ASTM F 899-07 or Titanium Alloy.

The instruments are offered in non-sterile condition.

Indications for Use:

K2 Medical Vascular Clamps are devices intended for temporary or partial occlusion of blood vessels during vascular surgical procedures.

Comparison with Predicate Device:

The results of non-clinical and bench testing indicates that the new device is completely comparable to the predicate devices. Biocompatibility and sterilization studies were successfully completed.

The K2 Medical product is similar to the predicate device in terms of technical characteristics, design, Indications for Use, Target population, where it is used, performance, biocompatibility, sterilisation method, mechanical safety characteristics as well as sizes and configurations. **Therefore it can be deemed substantially equivalent for its indicated use.**

Conclusion:

The presented data that was conducted on the K2 Medical Vascular Clamps shows in its results and in comparison to the predicate devices that the products are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

K2 Medical GmbH & Co.KG
C/O Mr. Peter Fetzner
Unter Buchsteig 3a
78532 Tuttlingen,
GERMANY

APR 30 2012

Re: K120492

Trade/Device Name: K2 Medical Vascular Clamp

Regulation Number: 21 CFR 870.4450

Regulation Name: Vascular Clamp

Regulatory Class: Class II

Product Code: DXC

Dated: February 13, 2012

Received: February 17, 2012

Dear Mr. Fetzner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

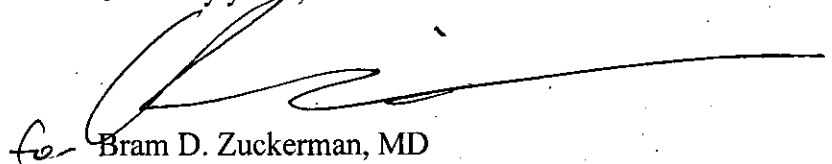
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a horizontal line.

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120492

Device Name: K2 Medical Vascular Clamps

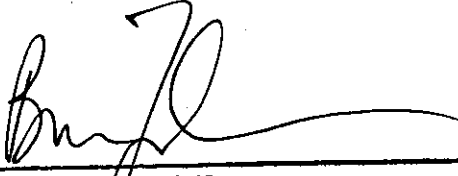
Indications For Use:

K2 Medical Vascular Clamps are devices intended for temporary or partial occlusion of blood vessels during vascular surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120492